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Registration Decision RD2015-19

Copper (present as Copper Octanoate)

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Registration Decision for Copper (Present as Copper Octanoate)

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the Pest Control Products Act and Regulations, is granting full registration for the sale and use of two technical grade active ingredients – Cueva TGAI and Cueva RTU TGAI – and eight end-use products – Cueva Commercial, Cueva Concentrate, Cueva Ready-to-Spray, Cueva RTU, Cueva RTU with Pull'N Spray Applicator, Cueva RTU with Quickpump Applicator, Cueva RTU with Wand Applicator, and Cueva RTU with Quick Connect Sprayer – containing the technical grade active ingredient copper (present as copper octanoate) to control or suppress various fungal and bacterial diseases on turf, nuts, as well as ornamentals, and a variety of fruit and vegetables in both the field and greenhouse.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

These products were first proposed for registration in the consultation document[1] Proposed Registration Decision PRD2015-12, *Copper (present as Copper Octanoate)*. This Registration Decision[2] describes this stage of the PMRA's regulatory process for copper (present as copper octanoate) and summarizes the Agency's decision and the reasons for it. The PMRA received no comments on PRD2015-12. This decision is consistent with the proposed registration decision stated in PRD2015-12.

For more details on the information presented in this Registration Decision, please refer to the Proposed Registration Decision PRD2015-12, *Copper (present as Copper Octanoate)* that contains a detailed evaluation of the information submitted in support of this registration.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable[3] if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its conditions of registration. The Act also requires that products have value[4] when used according to label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

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1 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

2 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

3 "Acceptable risks" as defined by subsection 2(2) of *Pest Control Products Act*.

4 "Value" as defined by subsection 2(1) of *Pest Control Products Act* "... the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (*a*) efficacy; (*b*) effect on host organisms in connection with which it is intended to be used, and (*c*) health, safety and environmental benefits and social and economic impact".

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (for example, children) as well as organisms in the environment. These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides and Pest Management portion of Health Canada's website at healthcanada.gc.ca/pmra.

What Is Copper (present as Copper Octanoate)?

Copper (present as copper octanoate) is a fatty acid salt (soap) that combines copper and octanoic acid. It is a contact fungicide and bactericide that can be applied to foliage to control or suppress various plant diseases on a broad range of agricultural and ornamental crops and turf grass. It is a new active ingredient in eight end-use products for commercial and domestic use.

Health Considerations

Can Approved Uses of Copper (present as Copper Octanoate) Affect Human Health?

Copper (present as copper octanoate) is unlikely to affect human health when used according to label directions.

Exposure to copper (present as copper octanoate) may occur when handling and applying the product, or coming into contact with treated surfaces. When assessing health risks, two key factors are considered: the levels where no health effects occur and the levels to which people may be exposed. Only uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

In laboratory animals, copper (present as copper octanoate) was of low acute toxicity via the oral, dermal and inhalation routes of exposure. Copper (present as copper octanoate) was also minimally irritating to the eyes, non-irritating to the skin, and not a dermal sensitizer. The toxicology profiles of the end-use products are no different than copper (present as copper octanoate).

The active component of toxicological concern with the majority of copper-containing pesticides is the copper ion, and most copper compounds, including copper (present as copper octanoate), can therefore be considered similar in terms of their toxicity. Copper is a naturally occurring metal that occurs in many foods including organ meats, seafood, beans, nuts and whole grains, and in drinking water. Copper is also an essential element in maintaining normal health in humans, with adverse effects more likely to result from copper deficiency rather than excess. Humans have efficient mechanisms in place to regulate copper in the body, and as such are readily able to clear excess copper from the body before harm is caused.

Residues in Water and Food

Dietary risks from food and water are not of concern.

Based on the ubiquitous nature of copper and the currently registered use patterns of various forms of copper on the labelled commodities, the use of copper (present as copper octanoate) is not expected to appreciably increase food residue levels of copper beyond the maximum residue limit (MRL) of 50 ppm specified for copper on all food commodities.

Risks in Residential and Other Non-Occupational Environments

Risk to residential users of domestic end-use products is not expected to be of concern due to the low toxicity of copper (present as copper octanoate) and the low potential for exposure expected when the products are applied according to label directions.

Occupational Risks from Handling the Commercial end-use products Containing Copper (present as Copper Octanoate)

Occupational risks are not of concern when the end-use products containing copper (present as copper octanoate) are used according to the label directions, which include protective measures.

Workers can come in direct contact with the commercial end-use products containing copper (present as copper octanoate) when handling the product, or come into contact with treated crops when entering treated areas before sprays have dried. The label has adequate precautionary measures including the requirement of personal protective equipment and precautionary and hygiene statements to minimize exposure. Taking into consideration these label statements, the number of applications and the expectation of the exposure period for workers, risks to these individuals are not a concern.

Environmental Considerations

What Happens When Copper (present as Copper Octanoate) Is Introduced Into the Environment?

When used according to label directions, copper (present as copper octanoate) does not pose an unacceptable risk to the environment.

Copper (present as copper octanoate) enters the environment when used for the control of fungal diseases on a variety of agricultural crops, ornamental plants and on turf. Minimal environmental exposure is expected from the use of copper (present as copper octanoate) in greenhouses. Once in the environment, copper (present as copper octanoate) dissociates into copper and fatty acids. Fatty acids occur naturally in the environment and degrade rapidly in the presence of microorganisms in both aquatic and terrestrial environments. Copper is an element that also occurs naturally in the environment, but it does not break down. The non-metallic copper is

highly reactive, especially in aquatic environments. The form in which copper is found depends on characteristics of its surroundings and the nature and concentration of other forms of copper present. The free non-metallic copper has a high sorption affinity for soil, sediments and organic matter, and copper applied to the surface is not expected to move readily into groundwater. Environmental concentrations can reflect naturally occurring and other sources of copper besides pesticides.

The use of copper (present as copper octanoate) is not expected to significantly increase environmental exposure to either copper or fatty acids. The environmental risks to non-target organisms have been previously assessed for environmental concentrations exceeding those for copper (present as copper octanoate) uses (Re-evaluation Decision RVD2010-05: *Copper Pesticides*, Re-evaluation Decision Document RRD2004-26: *Soap Salts*). At label rates, the use of copper (present as copper octanoate) presents a negligible risk to pollinators and aquatic vascular plants, but could pose a risk to birds, small wild mammals and aquatic organisms (freshwater and estuarine/marine invertebrates, fish and algae) if they are exposed to high enough concentrations. To minimize exposure to non-target organisms, spray buffer zones are specified on the label of the commercial product to protect freshwater and marine habitats adjacent to treated areas. Hazard statements are also specified on all product labels for birds, small wild mammals and aquatic organisms.

Value Considerations

What Is the Value of Cueva Commercial and the domestic products: Cueva Concentrate, Cueva Ready-To-Spray, Cueva RTU, Cueva RTU with Pull'n Spray Applicator, Cueva RTU with QuickPump Applicator, Cueva RTU with Wand Applicator and Cueva RTU with Quick Connect Sprayer?

Products containing copper (present as copper octanoate) control or suppress various diseases on many crops when used according to label directions. They are additional pest management tools useful in commercial or non-commercial sites, or for conventional or organic crop production.

The range of Cueva products containing copper (present as copper octanoate) consists of one commercial class and seven domestic class products. They are intended for managing various plant diseases on fruit crops, vegetable crops, and ornamental plants in the greenhouse and outdoors as well as on turf and tree nuts. The domestic class products may be applied through various types of spray attachments, including a standard garden hose.

The registration of copper (present as copper octanoate) products will provide growers with another broad spectrum fungicide/bactericide for both conventional and organic production as well as provide homeowners additional options for plant disease management in non-commercial settings. The registration of this active ingredient in Canada will address some of the pest management needs identified by growers. Copper (present as copper octanoate) has value in pest resistance management because it is considered to have a low risk of resistance development and could be used in an integrated pest management program.

Labels of registered pesticide products include specific instructions for use. Directions include risk reduction measures to protect human and environmental health. These directions must be followed by law.

The key risk reduction measures on the labels of the end-use products containing copper (present as copper octanoate) to address the potential risks identified in this assessment are as follows.

Key Risk-Reduction Measures

Human Health

Although the toxicological profiles of the commercial and domestic products raise no hazards of concern, the end-use product labels include a number of mitigation statements aimed at minimizing human exposure. The following statements are included on the commercial product label: "Mixers, loaders, applicators, and other handlers must wear long-sleeved shirt, long pants and shoes plus socks" and "DO NOT apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application." In addition, the commercial product label requires a restricted-entry interval of four hours to allow sprays to dry and requires that the product not be applied within one day of crop harvest. For the domestic end-use products, unnecessary exposures are to be minimized by including the statement, "DO NOT allow adults, children or pets to enter the treated area until sprays have dried" on all labels.

Environment

To mitigate potential exposure of aquatic organisms through spray-drift, spray buffer zones of 1 to 50 metres are required on the commercial product label to protect sensitive aquatic habitats. As well, hazard statements indicating toxicity to birds, small wild mammals and aquatic organism are required on product labels.

Other Information

The relevant test data on which the decision is based (as referenced in PRD2015-12, *Copper (present as copper octanoate)* are available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa). For more information, please contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra.infoserv@hc-sc.gc.ca).

Any person may file a notice of objection[5] regarding this registration decision within 60 days from the date of publication of this Registration Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticides and Pest Management portion of the Health Canada's website (Request a Reconsideration of Decision) or contact the PMRA's Pest Management Information Service.

[5] As per subsection 35(1) of the *Pest Control Products Act*.